DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 8, 2017

Navilyst Medical, Incorporated
Mr. Marion W. Gordon
Global Regulatory Affairs Project Manager
26 Forest Street
Marlborough, Massachusetts 01752

Re: K113198
Trade/Device Name: NMI Control Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector syringe
Regulatory Class: II
Product Code: DXT
Dated: October 28, 2011
Received: October 31, 2011

Dear Mr. Gordon

This letter corrects our substantially equivalent letter of November 28, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S6

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if Known): K113198

Device Name: NMI Control Syringe

Indications for Use:

The NMI Control Syringe is intended to be used for the intra-arterial or intravenous administration of radiographic contrast media.

Prescription Use (21 CFR 801 Subpart D) ☒ And/Or AND/OR Over-The-Counter Use: (21 CFR 801 Subpart C) ☐

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 11/29/11

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113198

K113198

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Navilyst Medical

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510(k) Summary for the NMI Control Syringe

Date prepared: 28 October 2011

A. Sponsor

Navilyst Medical, Inc.
26 Forest Street
Marlborough, MA 01752

B. Contact

Marion W. Gordon	or	Lorraine M. Hanley
Project Manager		Vice President
Global Regulatory Affairs		Global Regulatory Affairs
Phone: 508-658-7942		Phone: 508-494-1129

C. Device Name

Trade Name:	NMI Control Syringe
Common/Usual name:	Control Syringe
Classification Name:	Piston Syringe 21 CFR §880.5860, Class II
Classification Panel:	General Hospital

D. Predicate Device

Trade Name:	NAMIC Angiographic Control Syringe
Common/Usual name:	Control Syringe
Classification Name:	Piston Syringe 21 CFR §880.5860, Class II
Premarket Notification	K873955

E. Device Description

The NMI Control Syringes are manual control, piston type syringes consisting of a clear, calibrated, hollow barrel accommodating volumes of either 7 mL or 8 mL. As a manual control syringe, each configuration includes bilateral, external finger rings located on the proximal barrel shaft. The proximal thumb ring, located on the piston, in tandem with the external finger rings, allows for single handed movement to create aspiration and/or expulsion of fluids.

F. Intended Use

The NMI Control Syringe is intended to be used for the intra-arterial or intravenous administration of radiographic contrast media.

G. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed NMI Control Syringes have similar materials, design and components, and technological characteristics as the predicate control syringe.

H. Performance

No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. The performance evaluation of the NMI Control Syringes was conducted based upon a risk analysis and included testing conducted in accordance with the following international standards and FDA guidance document:

- ISO 7886-1, *Sterile hypodermic syringes for single use - Part 1: Syringes for manual use* (1993)
- ISO 594-2 *Conical Fittings with a 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment- Part 2: Lock Fittings* (1998)
- ANSI/AAMI/ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* (2007)
- ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process* (2009)
- AAMI/ANSI/ISO *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals* (2008)
- AAMI/ANSI/ISO 11601-1 *Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems, and packaging systems* (2006)
- AAMI/ANSI/ISO 11601-2 *Packaging for terminally sterilized medical devices Part 2: Validation requirements for forming, sealing and assembly processes* (2006)
- FDA's *FDA Guidance on the Content of Premarket Notification [510(k)] Submissions for Piston Syringes*, dated April 1993

I. Safety and Performance Testing

The successful results of the following key tests demonstrate that the proposed NMI Control Syringe met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.

Tests			
Alignment of Nozzle on End of Barrel	Freedom from Air Leakage past Piston	Lubricant (Quantity)	Piston Pull Out Force
Barrel Finger Grips	Freedom from Liquid Leakage past Piston	Nozzle Conical Fitting	Stroke Length
Cleanliness	Graduated Scale	Nozzle Lumen	Syringe Capacity
Dead Space	Length of Scale	Numbering of Scale	Zero Graduation and Fiducial Line Alignment
Fiducial Line	Limits for Acidity or Alkalinity	Piston (Plunger) Forces	
Fit of piston in barrel	Limits for Extractable Metals	Piston Assembly Design	

J. Conclusion

Results of performance testing according to recognized standards and in consideration to the responses posed in FDA's *Guidance on the CDRH Premarket Notification Review Program, 510(k) Decision Making Tree*, the proposed devices are determined to be substantially equivalent to the predicate device.